Remarks

In this communication, the specification has been amended at page 4, paragraph [0045]. The amendment to the specification is supported, for example, by claims 33, 37, and 38, as originally filed. No new matter has been added.

Claims 18, 22, 23, 25, 50, 52, and 53 have also been amended. Claims 22 and 23 have been amended to depend from amended claim 25; claim 50 has been amended to depend from claim 1. The amendments these claims is supported at, for example, paragraphs [0038]-[0040], and [0043]; Figures 4–9; and the claims as originally filed. No new matter has been added.

Claims 17 and 24 have been cancelled.

Upon entry of the current amendment, claims 1-16, 18-23, 25 and 50-57 will be pending. Reconsideration and allowance of the claims, as amended, and in light of the following remarks, are respectfully requested.

Objection to the specification

The Office action objected to the specification as failing to provide proper antecedent basis for the claimed subject matter (37 CFR 1.75(d)(1) and MPEP 608.01(o)). Applicants have amended the specification at paragraph [0045], to recite the upper limit of 75 kGy. In view of this amendment, Applicants believe that the objection has been overcome, and respectfully request that it be withdrawn.

Claim Rejections - 35 U.S.C. 112

The Office action rejected claims 52 and 53 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Office action stated that there is no basis in the original disclosure for the limitation that in the compressed state, the stent has a length that is twice a length, or more, of the stent in an expanded state.

Applicants have amended claims 52 and 53 to clarify the claimed subject matter. The amendment is supported by the specification, as detailed in previous communications

on the record, and Applicants believe that the amendment overcomes the stated rejection. Applicants respectfully request that the rejection be withdrawn.

Claim Rejections - 35 U.S.C. 103

Prior to discussing the merits of the obviousness rejections as set forth in the current Office action, an overview of the pending claims is presented to reiterate that different embodiments of bioresorbable stents are claimed. The features of these different embodiments must be appreciated to properly assess the patentability of the pending claims. Overall, the pending claims under consideration are directed to:

- Bioresorbable, self-expanding stents having a latticed network formed from a plurality of monofilaments (claims 1-16, 50, and 52-57)
- Bioresorbable, self-expanding stents having a fenestrated walled surface (claims 18-23, and 25)
- A method for using a bioresorbable, self-expanding stent (claim 51)

Claims 18-25

The Office action rejected claims 18-25 under 35 U.S.C. 103(a) as being unpatentable over Hogan (U.S. Patent No. 6,569,191; referred to herein as "Hogan") in view of Stack et al. (International Publication No. WO 91/17789; referred to herein as "Stack"). The rejection of claim 24 is moot as this claim has been cancelled. Rejection of claims 18-23 and 25 is traversed as failing to support a conclusion of *prima facie* obviousness.

For a claim to be rejected as *prima facie* obvious, the Office action must show the portions of the cited prior art that teach or suggest all features of the claim. The rejection, based on the cited Hogan and Stack references, does not support a showing of all of the features of Applicants' claims 18-23 and 25, including a "fenestrated walled surface."

The Office Action, at pages 4-5, states that, "As to the term "fenestrated" wall surface defined in claims 18 and 22-25, for example, the openings between the threads of the Hogan stent are fenestrations, making the wall "fenestrated," as broadly claimed." Applicants disagree with this conclusion, because it is believed that the Office action has

improperly assessed the Applicants' claims without viewing the claim terminology in context of the specification.

The Applicants' specification and claims make clear that stent embodiments wherein the stent has a "fenestrated" wall are different from stent embodiments wherein the stent has monofilaments braided to form a stent wall. The fenestrated embodiments are clearly described in the specification and claims as originally filed, see paragraphs [0013]-[0014] on pages 1-2; paragraphs [0049]-[0050] on pages 4-5; claims 18-24 and 39-48 as originally filed, and Figure 3. In particular, the "fenestrated" stent embodiments, as described and illustrated, have wall structures that include apertures or holes that are molded or cut into a wall; this is distinct from the braided monofilament embodiment. Applicants specifically directs Examiner to page 5, paragraph [0050], for exemplary clarification regarding these two embodiments, e.g., "The fenestrations are introduced into the tubular sheaths by cutting processes including, but not limited to, laser cutting and machining." See also original claim 45 which recites the step of, "cutting fenestrations into said tubular sheath."

Applicants' use of the terms "fenestration" and "fenestrated," in the present claims and specification, in referring to particular stent embodiments having apertures, holes, or windows that are molded, cut, or machined into a wall (as opposed to being apertures between braided monofilaments). Thus, these terms should be given the intended meaning in reviewing the claims for patentability. "When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the Applicant's invention and its relation to the prior art." *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

Taking into consideration the correct meaning of the term "fenestrated walled surface," the Office action has not established what portions, if any, of Hogan or Stack describe a stent having a "fenestrated walled surface" as recited in claims claim 18-23 and 25. Furthermore, claim 18 has been amended to recite the feature of wherein the stent is annealed and gamma-irradiated by exposure to gamma irradiation in an amount in the range of approximately 35 kGy to 75 kGy.

Because the Office action has not established that the cited references teach or suggest all the features as recited in the Applicants' claims, the requirements necessary for supporting a *prima facie* case of obviousness of claims 18-23 and 25 have not been met, and the outstanding rejection of these claims should be withdrawn.

Claims 1-3, 8-11, 16, 51 and 57

The Office action rejected claims 1-3, 8-11, 16, 51 and 57 under 35 U.S.C. 103(a) as being unpatentable over Hogan in view of Stack as applied to the rejection of claims 17-25, and further in view of Cotterman et al. (U.S. Patent Application No. 2002/0153511; herein referred to "Cotterman"). Rejection of these claims is traversed as failing to support a conclusion of *prima facie* obviousness.

In the least, the Office action fails to show that the cited references suggest or provide any motivation for using an amount of gamma irradiation in the range of approximately 35 kGy to 75 kGy for the preparation of bioresorbable self-expanding stents that include at least one biocompatible polymer, as detailed in the Applicants' pending claims. For a proper *prima facie* case of obviousness rejection, the Office action must articulate the motivation or suggestion to combine selected portions of the cited references in such a manner as to provide for the Applicants' claimed invention. Because this has not been provided the rejection is improper and should be withdrawn.

Claims 1-3, 8-11, 16, 51 and 57 of the invention are directed to self-expanding stents that include a latticed network of a plurality of monofilaments, the monofilaments including at least one biocompatible polymer, wherein the stent is annealed and gamma-irradiated by exposure to gamma irradiation in an amount in the range of approximately 35 kGy to 75 kGy.

While the teachings of Hogan and Stack are said to describe particular features of the invention, they do not teach the features of irradiating the stent with this dose of gamma irradiation in a range as recited in the Applicants' claims.

In an attempt to cure the deficiencies of Hogan and Stack, and to establish a *prima facie* case of obviousness against the pending claims, the Office action has presented Cotterman. Cotterman –whose teaching is not directed in any manner to the fabrication

or medical use of stents– is cited as a reference to remedy the Hogan and Stack failure to teach gamma-irradiating a stent by exposure to gamma irradiation in an amount in the range of approximately 35 kGy to 75 kGy.

The Applicants' claims recite particular types of stents, which are understood to be a part of a much larger universe of "stents" in the medical arts. In particular, the stent of the Applicants' claims is self expanding, and includes a biodegradable polymer, and according to certain specific embodiments, may be braided, fenestrated, or sized. Cotterman is silent with regard to these particular stent features. The Office action has not shown that Cotterman suggests, or provides any motivation for, using a dose of irradiation in the claimed range, for the preparation of the types of stents as recited in the Applicants' claims.

Rather than showing any suggestion or motivation, the Office action has merely identified and then combined particular teachings of Cotterman referring to a "stent" (paragraph [0043]) and gamma irradiation in a dose of 39 kGy (paragraph [0098]). Applicants do not believe that this rises to the level of suggestion necessary for arriving at the claimed invention.

Cotterman is not directed to the preparation and use of stents, but rather is directed toward packaging technology. Cotterman describes using an oxygen scavenging system in combination with actinic radiation for packaging and sterilizing an oxygen sensitive product in a container (see Abstract). In particular, Cotterman teaches that the actinic radiation should be applied to sterilize the container and **trigger** the oxygen scavenger in the article. See, for example, paragraph 44, ""Trigger" and the like herein means that process defined in U.S. Patent No. 5,211,875, wherein oxygen scavenging is initiated (i.e., activated) by exposing an article such as a film to actinic radiation, such as ionizing radiation such as gamma radiation, having a wavelength of less than about 750 nm at an intensity of at least about 1.6 mW/cm2 or an electron bean at a dose of at least 0.2 megarads (MR)..."

Example 2 ([0098]) of Cotterman teaches that gamma irradiation in an average dose of 39 kGy was provided the 9-layer film of Example 1. However, it is noted that in Example 2 no medical product was *actually* irradiated. With regard to this dose of

gamma irradiation Cotterman states, "This dose was selected to be representative of a level useful for sterilization of packaged medical products."

Cotterman, referring to paragraph [0043], provides only a generic list of potential "medical products" which includes "stents" among other disparate medical products such as needles, bandages, scalpels, ointments, plasma, intravenous solutions, shoe coverings, etc. The Office action has not presented any showing of a suggestion, motivation, or any other reason, as to why a stent -- particularly one that includes bioabsorbable material -- should be chosen among this lengthy list of disparate "medical products" to be subject to an amount of gamma irradiation in the range as recited in the present claims.

Overall, the Office action has provided no showing of why one of skill in the art would have been motivated to combine the teaching of Hogan and Stack (which are directed toward the construction and use of bioabsorbable polymers) with that of Cotterman (which is directed toward packaging technology using oxygen scavengers) to provide a self-expanding bioresorbable stent as recited in the present claims. In this regard, the process of combining Cotterman with Hogan and Stack to establish a *prima facie* case of obviousness lacks support.

Without a showing of such a motivation, the outstanding rejection of claims 1-3, 8-11, 16, 51 and 57 is not supported. The reconstruction of Applicants' claimed subject matter from these prior art references, the basis of the Office actions obviousness rejection, can only be explained upon review of the Applicants' specification and claims.

In view of these remarks, Applicants respectfully assert that the requirements for properly establishing a *prima facie* case of obviousness have not been met. Applicants respectfully request that this rejection be withdrawn.

Claims 4-7, 12-15, 52-55, and 56

The Office action rejected claims 4-7, 12-15, 52-55, and 56 under 35 U.S.C. 103(a) as being obvious over a combination of Hogan, Stack, Cotterman, along with other references. Specifically, Hogan in view of Stack and Cotterman and further in view of:

- Thompson et al. (U.S. Patent No. 5,957,974; herein referred to as "Thompson") were used to reject claims 5-7 and 13-15.
- Amstrup (U.S. Patent No. 5,476,508; herein referred to as "Amstrup") were used to reject claims 4 and 12.
- Turnlund et al. (U.S. Patent No. 5,629,077; herein referred to as "Turnlund") were used to reject claim 56.
- Shaolian et al. (U.S. Patent No. 6,261,316; herein referred to as "Shaolian") were used to reject claims 52-55.

Rejection of these claims is also traversed as failing to support a conclusion of *prima facie* obviousness for at least the reasons as described in the Applicants' response to the rejection of claims 1-3, 8-11, 16, 51 and 57.

Neither Thompson, Amstrup, Turnlund, nor Shaolian describe annealing and gamma-irradiating a bioresorbable stent by exposure to gamma irradiation in an amount in the range of approximately 35 kGy to 75 kGy.

Furthermore, with regard to the rejection of claims 52-55, the Office action has not addressed all of claimed features that are believed to be taught by Shaolin.

In particular, the Office action has not stated what portions of Shaolin are believed to specifically teach the particular self-expansion forces in relation to the lengths and diameters of the bioabsorbable stents in compressed and expanded states. With regard to compression resistance Shaolin is silent.

Shaolin precisely teaches that, "the different zones can be provided with a different radial expansion force, such as ranging from about 2 lbs. to about 8 lbs." Based on the calculations of Office actions, this range is from about 71 N to about 285 N, which is much greater than the forces of 4, 6, 8, or 10 N as recited in the pending claims.

Applicants traverse the Office action's statement that, "It would have been obvious to provide the claimed expansion force for the Hogan stent so that it too would have this advantage." Shaolin is silent with regard to self-expanding stents prepared from bioabsorbable materials and makes no suggestion to apply any of its teaching for the preparation of bioresorbable stents as claimed by the Applicants.

Accordingly, Applicants respectfully request that the rejection of claims 4-7, 12-15, 52-55, and 56 be withdrawn.

Claim 50

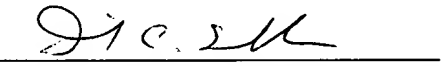
The Office action rejected claim 50 under 35 U.S.C. 103(a) as being unpatentable over Hogan in view of Stack, and further in view of Turnlund.

Applicants have amended claim 50 to be dependent from claim 1. Applicants believe this amendment overcomes the rejection for at least the reasons as discussed in the response to the rejection of claims 1-3, 8-11, 16, 51 and 57. Applicants respectfully request that the rejection of claim 50 be withdrawn.

In view of the present amendments and remarks, Applicants submit that the outstanding rejections have been either overcome or should otherwise be withdrawn.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

By: 

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